

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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ALLERGAN, INC., ALLERGAN  
PHARMACEUTICALS IRELAND  
UNLIMITED COMPANY, and ALLERGAN  
USA, INC.,

Plaintiffs,

v.

REVANCE THERAPEUTICS, INC. and  
AJINOMOTO ALTHEA, INC. d/b/a  
AJINOMOTO BIO-PHARMA SERVICES,

Defendants.

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C.A. No. 21-1411-RGA

**REPORT AND RECOMMENDATION**

Presently pending before the Court is Defendants' Motion to Dismiss the First Amended Complaint Under Federal Rule of Civil Procedure 12(b)(1) and/or Rule 12(b)(6). (D.I. 22.) As announced from the bench on July 7, 2022, I recommend that Defendants' motion be DENIED.

**I. DISCUSSION**

My Report and Recommendation was announced from the bench as follows:

This is my Report and Recommendation on the pending motion to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). I will summarize the reasons for my recommendation in a moment. But before I do, I want to be clear that my failure to address a particular argument does not mean that I did not consider it. We have considered all of the arguments. I also note that, while we will not be issuing a separate written recommendation, we will issue a written document incorporating a transcript of the recommendation that I am about to make.

For the following reasons, I recommend that the Court deny Defendants' motion to dismiss.

Plaintiffs Allergan, Inc., Allergan Pharmaceuticals Ireland Unlimited Company, and Allergan USA, Inc. (collectively, “Allergan” or “Plaintiffs”) market the drugs BOTOX® and BOTOX® Cosmetic, which contain botulinum toxin. BOTOX® and BOTOX® Cosmetic are indicated for multiple therapeutic and aesthetic indications including prophylaxis of migraines and improvement in the appearance of forehead lines.<sup>1</sup> Plaintiffs own or are the exclusive licensees of numerous patents covering aspects of their formulations, manufacturing processes, and assays.<sup>2</sup>

Defendant Revance Therapeutics, Inc. (“Revance”) has developed its own botulinum toxin product, called DaxibotulinumtoxinA for Injection (“DAXI”).<sup>3</sup> In November 2019, Revance filed a Biologics License Application (“BLA”) with the FDA, through which Revance seeks approval to market DAXI.<sup>4</sup> The FDA accepted Revance’s BLA on February 5, 2020, and it initially set a target action date of November 25, 2020.<sup>5</sup> However, on November 24, 2020, the FDA deferred its decision due to COVID-related travel restrictions that prevented it from inspecting Revance’s manufacturing facility, which is one of the final steps that needs to occur before approval.<sup>6</sup>

The FDA inspected Revance’s manufacturing facility in June and July 2021.<sup>7</sup> On July 2, 2021, the FDA issued a Form 483 listing deficiencies identified during the on-site inspection.<sup>8</sup> Following issuance of the Form 483, Revance’s CEO stated during

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<sup>1</sup> (D.I. 16 (FAC) ¶¶ 20–21.)

<sup>2</sup> (*Id.* ¶¶ 23, 26, 30, 34, 38, 42.)

<sup>3</sup> (*Id.* ¶¶ 48–49.)

<sup>4</sup> (*Id.* ¶ 65.)

<sup>5</sup> (*Id.* ¶ 66.)

<sup>6</sup> (*Id.* ¶¶ 67–69.)

<sup>7</sup> (*Id.* ¶ 70.)

<sup>8</sup> (*Id.* ¶¶ 70, 73.)

a conference presentation that the inspection was “a very typical inspection.”<sup>9</sup>

In a press release in August 2021, Revance stated that it was “actively building inventory and preparing for commercial launch.”<sup>10</sup> And in a press release on October 12, 2021, Revance stated that it “remains confident in the quality of its BLA submission and continues to anticipate FDA approval in 2021.”<sup>11</sup>

On October 15, 2021, Revance announced that the FDA had issued a Complete Response Letter (“CRL”) indicating that the BLA could not be approved in its present form due to deficiencies related to the FDA’s onsite inspection.<sup>12</sup> According to Revance, “[n]o other deficiencies were identified in the CRL.”<sup>13</sup>

In a November 9, 2021, SEC filing, Revance stated that it had received additional information from the FDA and that the company planned to file a Type A meeting request with the FDA.<sup>14</sup> [Also on that day, Revance’s CEO] stated that the FDA had provided Revance with an Establishment Inspection Report that included feedback and an approval pathway for DAXI.<sup>15</sup> He further stated that the company was looking at “all different avenues” to launch “as soon as possible.”<sup>16</sup>

Plaintiffs filed this case on October 1, 2021, and they filed their FAC on November 24, 2021. The FAC names Revance as a defendant, and it also names Ajinomoto Althea, Inc. (“ABPS”), with

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<sup>9</sup> (*Id.* ¶ 71.)

<sup>10</sup> (*Id.* ¶ 79, Ex. 35.)

<sup>11</sup> (*Id.* ¶ 72, Ex. 29.)

<sup>12</sup> (*Id.* ¶ 73, Exs. 30, 31.)

<sup>13</sup> (*Id.*, Ex. 32 at 31, Ex. 33 at 5 (“[T]he CRL is not related to our clinical data package or our product anticipated label.”).)

<sup>14</sup> (*Id.* ¶ 74, Ex. 32.)

<sup>15</sup> (*Id.* ¶ 75, Ex. 33.)

<sup>16</sup> (*Id.* ¶ 76, Ex. 33 at 9.)

which Relevance has entered into a drug product manufacturing agreement.<sup>17</sup>

The FAC contains twelve counts. The parties refer to six counts (Counts I, III, V, VII, IX, and XI) as the stockpiling counts. Those counts allege that Defendants' manufacture, use, or importation into the United States of batches of the DAXI product in preparation for launch and substrates used to assay the product has infringed six of Plaintiffs' patents: U.S. Patent No. 11,033,625 (the '625 patent), which covers pharmaceutical compositions containing botulinum toxin; U.S. Patent No. 11,147,878 (the '878 patent), which covers methods of stabilizing a botulinum toxin; U.S. Patent Nos. 7,354,740 (the '740 patent), 8,409,828 (the '828 patent), and 11,124,786 (the '786 patent), all of which cover processes for purifying a botulinum toxin; and U.S. Patent No. 7,332,567 (the '567 patent), which covers substrates for botulinum toxin activity assays.

The parties refer to the remaining six counts (Counts II, IV, VI, VIII, X, and XII) as the DJ counts. Through those counts, Plaintiffs seek declaratory judgments that Defendants' manufacture, use, offer for sale, or sale within the United States of the DAXI product will infringe the same six patents.

On December 17, 2021, Defendants filed a motion to dismiss the FAC under Rule 12(b)(1) for lack of subject matter jurisdiction and under Rule 12(b)(6) for failure to state a claim.<sup>18</sup> After the motion was fully briefed, the Court granted the parties leave to file supplemental briefing, which they did on June 7 and June 21, 2022.<sup>19</sup> Plaintiff requested argument and I heard oral argument earlier today.

I'll start with Defendants' contention that the Court lacks subject matter jurisdiction over all twelve counts. The first step in a subject matter jurisdiction analysis is determining whether the "12(b)(1) motion presents a 'facial' or a 'factual' attack on the claim at issue, because that distinction determines how the pleading must

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<sup>17</sup> (*Id.* ¶ 58.)

<sup>18</sup> (D.I. 22.)

<sup>19</sup> (D.I. 23, 26, 27, 33, 34.)

be reviewed.”<sup>20</sup> The Third Circuit has explained the differences between a facial and a factual attack [as follows:

A facial attack, as the adjective indicates, is an argument that considers a claim on its face and asserts that it is insufficient to invoke the subject matter jurisdiction of the court because, for example, it does not present a question of federal law, or because there is no indication of a diversity of citizenship among the parties, or because some other jurisdictional defect is present. Such an attack can occur before the moving party has filed an answer or otherwise contested the factual allegations of the complaint. . . . A factual attack, on the other hand, is an argument that there is no subject matter jurisdiction because the facts of the case—and here the District Court may look beyond the pleadings to ascertain the facts—do not support the asserted jurisdiction. So, for example, while diversity of citizenship might have been adequately pleaded by the plaintiff, the defendant can submit proof that, in fact, diversity is lacking. . . . In sum, a facial attack “contests the sufficiency of the pleadings,” *In re Schering Plough Corp.*, [678 F.3d 235, 243 (3d Cir. 2012)], “whereas a factual attack concerns the actual failure of a [plaintiff’s] claims to comport [factually] with the jurisdictional prerequisites.” *CNA v. United States*, 535 F.3d 132, 139 (3d Cir. 2008) (internal quotation marks omitted) (alterations in original).

In reviewing a facial attack, “the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff.” *In re Schering Plough Corp.*, 678 F.3d at 243 (quoting *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000)) (internal quotation marks omitted). Thus, a facial attack calls for a district court to apply the same standard of review it would use in considering a motion to dismiss under Rule

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<sup>20</sup> *Constitution Party v. Aichele*, 757 F.3d 347, 357 (3d Cir. 2014); see also *Mitek Sys., Inc. v. United Servs. Auto. Ass’n*, 34 F.4th 1334, 1342 (Fed. Cir. 2022) (vacating dismissal for lack of subject matter jurisdiction and remanding for further proceedings where the district court was “unclear in identifying whether it was treating the Rule 12(b)(1) motion as a facial challenge or as a factual challenge, . . . and the parties themselves have been unclear about this”).

12(b)(6), *i.e.*, construing the alleged facts in favor of the nonmoving party. *Id.* This is in marked contrast to the standard of review applicable to a factual attack, in which a court may weigh and “consider evidence outside the pleadings.” *Gould Elecs. Inc.*, 220 F.3d at 176 (citing *Gotha v. United States*, 115 F.3d 176, 178–79 (3d Cir.1997)).]<sup>21</sup>

Defendants’ briefing contends that they are mounting a factual attack.<sup>22</sup> But Defendants failed to submit any evidence (*i.e.*, affidavits, testimony, or other evidentiary materials) with their opening brief to contradict the FAC’s factual allegations in support of subject matter jurisdiction. Rather, Defendants’ briefs focus on what they contend is the FAC’s failure to allege sufficient jurisdictional facts.<sup>23</sup> That suggests a facial challenge.<sup>24</sup>

Compounding the confusion, Plaintiffs insist that Defendants’ attack is facial—which would restrict the Court’s review to the allegations and documents referred to in the FAC—yet Plaintiffs submitted hundreds of pages of exhibits in opposing Defendants’ motion.<sup>25</sup> What’s more, most of those exhibits did not exist at the time Plaintiffs filed the FAC and therefore have limited relevance to the question of whether subject matter jurisdiction existed at the time of the FAC.<sup>26</sup>

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<sup>21</sup> *Aichele*, 757 F.3d at 358.

<sup>22</sup> (D.I. 23 at 7.)

<sup>23</sup> (*See* D.I. 23 at 7 (“[T]he FAC fails to demonstrate subject matter jurisdiction.”); *id.* at 8 (“Allergan did not and cannot allege sufficient facts . . . .”); *id.* at 9 (“Similarly, Allergan’s allegations fail to show . . . .”); *id.* at 12 (“[T]he FAC fails to establish . . . .”); *id.* at 12 (“The FAC contains two allegations . . . both of which fail to establish subject matter jurisdiction.”).)

<sup>24</sup> *See Aichele*, 757 F.3d at 359 (“A factual attack requires a factual dispute . . . .”); *see also TSMC Tech., Inc. v. Zond, LLC*, No. 14-721-LPS-CJB, 2015 WL 661364, at \*3 (D. Del. Feb. 13, 2015) (treating a challenge as facial when the movant’s “emphasis [was] on why the allegations in the Complaint (and [a letter], attached as an exhibit to the Complaint), even accepted as true, [did] not demonstrate that a case or controversy exist[ed]”).

<sup>25</sup> (D.I. 26, Exs. 1–2; D.I. 33, Ex. 3–10.)

<sup>26</sup> *See Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 906 (Fed. Cir. 2014) (“[P]ost-complaint facts cannot create jurisdiction where none existed at the time of filing.”).

Here is how I see this: The motion presently before the Court argues that subject matter jurisdiction was lacking at the time Plaintiffs filed the FAC. Defendants failed to submit any evidence in support of their motion, and they are essentially saying that the FAC allegations, even accepted as true, are insufficient to demonstrate subject matter jurisdiction. In light of that, I will consider Defendants' motion as a facial challenge. Accordingly, I will consider the allegations and documents attached to the FAC and view them in the light most favorable to Plaintiffs.<sup>27</sup>

I'll now turn to Defendants' argument that the Court lacks subject matter jurisdiction over the stockpiling counts. Defendants say that the Court lacks jurisdiction because they might never sell the product they are alleged to have stockpiled. To put it bluntly, that argument is a nonstarter. You don't have to sell a product to infringe a patent. It is an act of patent infringement to make or import a patented product or to use a patented method.<sup>28</sup> The FAC alleges that Defendants have already done all of those things in the course of making the stockpiled batches.

Defendants alternatively contend that the Court lacks subject matter jurisdiction because it might in the future "utilize" the batches it is alleged to have stockpiled "to support its response to the [FDA]."<sup>29</sup> According to Defendants, their past activities are therefore shielded by 35 U.S.C. § 271(e)(1), which states that it is not an act of infringement to make, use, or import a patented invention "solely for uses reasonably related to the development and submission of information" to the FDA.

That argument is also a nonstarter, for at least three reasons. First, Defendants have provided no support for the proposition that application of the statutory safe harbor implicates the Court's subject matter jurisdiction, and I am unaware of any. Second, the FAC alleges—citing to Revance's own statements—that Revance was "actively building inventory" in preparation for "commercial

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<sup>27</sup> At oral argument, Plaintiffs accurately pointed out that jurisdiction also needed to exist at the time the original complaint was filed. *See Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, 599 F.3d 1377, 1383 (Fed. Cir. 2010). But that's beside the point. Subject matter jurisdiction needs to be present at all stages of a case, and I take Defendants' argument to be that jurisdiction was lacking at the time of the FAC.

<sup>28</sup> 35 U.S.C. § 271(a).

<sup>29</sup> (D.I. 23 at 14.)

launch.”<sup>30</sup> Viewed in the light most favorable to Plaintiffs, that allegation is sufficient to support a plausible inference that Revance did not make and import the batches in question “solely for uses reasonably related to” its FDA submission.<sup>31</sup>

Third, insofar as Defendants contend that a drug manufacturer may escape infringement liability for making and importing commercial-sized drug batches with the intent to sell them if it later submits data regarding those batches to the FDA, Defendants have cited no case supporting that proposition and I am unaware of any.<sup>32</sup> For those reasons, I recommend that the Court deny Defendants’ request to dismiss the stockpiling claims for lack of jurisdiction.

I’ll now turn to Defendants’ argument that the Court lacks subject matter jurisdiction over the DJ counts. As noted earlier, Plaintiffs seek declaratory judgments that Defendants’ future making, using, importing, and selling of DAXI will infringe Plaintiffs’ patents.

The Declaratory Judgment Act, 28 U.S.C. § 2201(a), provides that “[i]n a case of actual controversy within its jurisdiction, . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.” The phrase “case of actual controversy” refers to the type of “Cases” and “Controversies” that are justiciable under Article III of the Constitution.<sup>33</sup>

To meet the case or controversy requirement, a dispute must be “‘definite and concrete, touching the legal relations of parties having adverse legal interests’; and . . . ‘real and substantial’ and ‘admi[t] of specific relief through a decree of a conclusive character,

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<sup>30</sup> (FAC ¶ 79.)

<sup>31</sup> *Cf. Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1339 (Fed. Cir. 2019) (holding that when the asserted patent covers methods of manufacture, “[t]he relevant inquiry . . . is not *how* [the defendant] used each batch it manufactured, but whether each act of manufacture was for uses reasonably related to submitting information to the FDA”).

<sup>32</sup> *Cf. id.* at 1340 n.3 (rejecting contention that “simply submitting information about a drug substance lot to the FDA brings the manufacture of that lot within the Safe Harbor”).

<sup>33</sup> *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).



as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.”<sup>34</sup> The Supreme Court has recognized that its precedents “do not draw the brightest of lines between those declaratory-judgment actions that satisfy the case-or-controversy requirement and that do not,” and that, where jurisdiction is being assessed based on the complaint, “[b]asically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.”<sup>35</sup>

Defendants contend that the FAC fails to allege facts showing a controversy of sufficient “immediacy” and “reality.” When assessing “immediacy,” courts consider “how far in the future the potential infringement is, whether the passage of time might eliminate or change any dispute, and how much if any harm the potential infringer is experiencing, at the time of suit, that an adjudication might redress.”<sup>36</sup> When assessing “reality,” courts examine “any uncertainties about whether the [accused] will take an action that will expose it to potential infringement liability and, if so, exactly what action.”<sup>37</sup> Determining whether a controversy is of sufficient immediacy and reality is fact specific and must be determined on a case-by-case basis by considering the totality of the circumstances.<sup>38</sup>

Having examined the totality of the allegations, I conclude that the FAC alleges a controversy of sufficient immediacy and reality. Plaintiffs say that DAXI and the process for manufacturing it infringe Plaintiffs’ patents. The FAC alleges that shortly before this action was filed, Revance told the public that it was actively building inventory of DAXI in preparation for a launch. That fact alone is probably enough to satisfy the case or controversy

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<sup>34</sup> *Id.* (citing *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937)).

<sup>35</sup> *Id.* (citation omitted); *Mitek*, 34 F.4th at 1340.

<sup>36</sup> *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1278 (Fed. Cir. 2014) (quotation omitted).

<sup>37</sup> *Id.* (quotation omitted).

<sup>38</sup> *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, No. 16-1243-RGA, 2017 WL 2559735, at \*1 (D. Del. June 13, 2017).

requirement.<sup>39</sup> But I do not need to decide that because there is more. For example, the FAC also alleges that Revance made public statements that it anticipated FDA approval in 2021. Those facts, viewed in the light most favorable to Plaintiffs, suggest that even Defendants thought that FDA approval was imminent.

Defendants point out that those things happened before the FDA issued the CRL in October 2021 and that when the FAC was filed in November, it was uncertain if and when the BLA would ever be approved. Defendants also point out that Revance has up to a year to submit a response to a CRL, and because Revance's response to the FDA may include changes to DAXI and the process for making it, the facts relevant to infringement are fluid and indeterminate and thus fail the reality requirement.

I reject Defendants' position. As an initial matter, I do not think that the mere fact that a CRL was issued makes this dispute nonjusticiable. [W]e don't know what was in the [CRL], and we don't know what the FDA was requiring from Revance in terms of a response. The FAC does allege, however, that the CRL related to issues discovered during the onsite inspection (as opposed to the clinical data or proposed product label) and that, even after receiving the Form 483 report regarding the onsite inspection, Revance told the public that it still expected approval in 2021. Those facts, viewed in the light most favorable to Plaintiffs, permit a reasonable inference that Revance thought it would not have to change its product to remediate whatever deficiencies were identified in the onsite inspection. As noted during oral argument, I find ironic Defendants' position that uncertainties about when Revance would respond to the CRL and what it would need to submit make this dispute nonjusticiable. If Defendants actually thought in November 2021 that the FDA's identified approval pathway required changes to the product and/or process that are material to infringement or that it might take a year for Revance to put together its response, one might have expected Revance to mount a true factual challenge and submit evidence regarding its interactions with the FDA. It did not.

At a minimum, Plaintiffs are entitled to seek a declaration that the product that Defendants already produced would infringe if

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<sup>39</sup> See *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 881 (Fed. Cir. 2008) (concluding that the immediacy requirement does not necessitate that a party "have engaged in the actual manufacture or sale of a potentially infringing product," but that "there must be a showing of 'meaningful preparation' for making or using that product" (quoting *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988))).

imported or sold. If [Revance] thought that the changes requested by the FDA might result in [it] not being able to sell its alleged stockpile, one might have thought [it] would have submitted evidence of that fact. It did not.<sup>40</sup>

To be clear, I am not putting the burden on Defendants to put forth evidence. Plaintiffs retain the burden to allege facts that establish that subject matter jurisdiction exists. I am merely pointing out that because Defendants did not submit evidence, this is a facial challenge and I must view the FAC in the light most favorable to Plaintiffs. And I conclude that it adequately alleges a controversy of sufficient immediacy and reality.

This case is distinguishable from the *Juno Therapeutics*, *Clarus Therapeutics*, and *Teva Pharmaceuticals* cases cited by Defendants.<sup>41</sup> Among other differences, those cases didn't involve an allegation of past infringement or an allegation that the defendants had already manufactured infringing product that [they] planned to sell.<sup>42</sup> The facts [in this case] permit a reasonable inference that FDA approval was imminent.

I conclude that a case of actual controversy existed as of the filing of the FAC. For those reasons, I recommend that the Court deny Defendants' request to dismiss the declaratory judgment claims for lack of jurisdiction.

Defendants also contend that Plaintiffs would suffer no harm or prejudice if the court waited to hear this case until after the FDA's approval decision and that doing so would further judicial

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<sup>40</sup> As noted above, subsequent factual developments cannot create jurisdiction over a claim if none existed at the time of filing. I note, however, that Plaintiffs submitted evidence suggesting that Revance has already responded to the CRL and that it has told the public that it still hopes to use the product it has already produced.

<sup>41</sup> *Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, No. 17-12087-ADB, 2018 WL 10246999, at \*7 (D. Mass. Sept. 27, 2018); *Juno Therapeutics, Inc.*, 2017 WL 2559735, at \*2; *Clarus Therapeutics, Inc. v. Lipocine, Inc.*, No. 15-1004-RGA-MPT, 2016 WL 5868065, at \*3 (D. Del. Oct. 6, 2016).

<sup>42</sup> See *Teva Pharms.*, 2018 WL 10246999, at \*7 ("Plaintiffs do not dispute that all actions that Defendant has taken to prepare and submit its BLA for galcanezumab fall within the Safe Harbor of the Hatch-Waxman Act."); *Juno Therapeutics, Inc.*, 2017 WL 2559735, at \*2 (noting that Plaintiffs did not dispute that all of Defendant's activities prior to the filing of the action were "related to seeking FDA approval"); *Clarus Therapeutics*, 2016 WL 5868065, at \*3 (noting that the defendants were not alleged to have committed infringement prior to the filing of the complaint).

economy.<sup>43</sup> I'm not sure what Defendants' point is. Defendants haven't moved for a stay, and the Court has jurisdiction over the stockpiling claims and a duty to exercise it. As for the declaratory judgment claims, Defendants' argument might be viewed as a request that the Court use its discretion to decline to exercise jurisdiction. I would reject that request. The Court is already going to hear the stockpiling claims. It will promote judicial economy to hear both the stockpiling claims and the DJ claims together. Indeed, as Defendants' counsel pointed out during oral argument today, it makes no sense to litigate the DJ and stockpiling claims piecemeal.

Defendants cite the *Abraxis*<sup>44</sup> case, apparently for the proposition that the Federal Circuit has the ability to vacate cases for lack of jurisdiction even after the district court holds a trial and enters judgment. That is true, but that is not a reason for a district court to decline to hear a case that is otherwise properly before the court. If Defendants' point is that subject matter jurisdiction must exist at the time a suit is filed and thereafter, I agree. As explained above, it did in this case.

Turning to Defendants' request to dismiss the claims under Rule 12(b)(6), I am not going to read into the record my understanding of the legal standard that applies to such a motion, or how that standard has been applied in the context of pleading infringement. I set forth a recitation of the applicable legal standards in my Report and Recommendation in *Boston Fog, LLC v. Ryobi Technologies, Inc.*, No. 19-2310-LPS-JLH, 2020 WL 1532372, at \*3 (D. Del. Mar. 31, 2020).<sup>45</sup> And I incorporate that discussion by reference.

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<sup>43</sup> (D.I. 23 at 5–7.)

<sup>44</sup> *Abraxis Bioscience, Inc. v. Navinta LLC*, 625 F.3d 1359, 1362–63 (Fed. Cir. 2010).

<sup>45</sup> *Bos. Fog, LLC v. Ryobi Techs., Inc.*, No. 19-2310-LPS-JLH, 2020 WL 1532372, at \*3 (D. Del. Mar. 31, 2020), *adopted*, 2020 WL 8079820 (June 12, 2020). A defendant may move to dismiss a complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. “To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible on its face when the complaint contains “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*, 550 U.S. at 556). A possibility of relief is not enough. *Id.* “Where a complaint pleads facts that are ‘merely

Determining whether a claim is plausible is a “context-specific task that requires the reviewing court to draw on its judicial experience and common sense.”<sup>46</sup> I conclude that the allegations set forth in the FAC are sufficient to put Defendants on notice of the infringing activity. The FAC specifically identifies an accused product, and it alleges that the product and the process of manufacturing the product meet every limitation of at least one claim in each of the asserted patents. It also points to SEC filings and other exhibits that demonstrate Plaintiffs’ view as to how at least some of the claim elements of a representative claim from each patent are met. Under these circumstances, I conclude that the infringement claims are plausible.<sup>47</sup>

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consistent with’ a defendant’s liability, it ‘stops short of the line between possibility and plausibility of entitlement to relief.’” *Id.* (quoting *Twombly*, 550 U.S. at 557).

In determining the sufficiency of the complaint under the plausibility standard, all “well-pleaded facts” are assumed to be true, but legal conclusions are not. *Id.* at 679. “[W]hen the allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency should be exposed at the point of minimum expenditure of time and money by the parties and the court.” *Twombly*, 550 U.S. at 558 (quotation omitted).

A complaint sufficiently pleads direct patent infringement when it puts the defendant “on notice of what activity . . . is being accused of infringement.” *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1350 (Fed. Cir. 2018) (quoting *K-Tech Telecomms., Inc. v. Time Warner Cable, Inc.*, 714 F.3d 1277, 1284 (Fed. Cir. 2013)); *see also BioMérieux, S.A. v. Hologic, Inc.*, No. 18-21-LPS, 2018 WL 4603267, at \*3 (D. Del. Sept. 25, 2018). There is no requirement that the plaintiff “plead facts establishing that each element of an asserted claim is met.” *Nalco*, 883 F.3d at 1350 (quoting *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1335 (Fed. Cir. 2012)).

The Federal Circuit has further directed that, at this stage of the litigation, the plaintiff is “entitled to all inferences in its favor on its theory [of infringement].” *Id.* at 1349.

<sup>46</sup> *Iqbal*, 556 U.S. at 679.

<sup>47</sup> *See Align Tech., Inc. v. 3Shape A/S*, 339 F. Supp. 3d 435, 444 (D. Del. 2018) (finding complaint sufficient where it alleged that the accused products practiced a representative claim and provided examples drawn from product documentation demonstrating that the accused product possessed at least some of the requirements of the representative claim); *see also Vitaworks IP, LLC v. Prinova US LLC*, No. 19-2260-CFC, 2020 WL 7771040, at \*2 (D. Del. Dec. 30, 2020) (denying motion to dismiss notwithstanding plaintiff’s contention that the complaint failed to allege facts showing how the accused process practiced each step of the claimed method); *Dynamic Data Techs., LLC v. Brightcove Inc.*, No. 19-1190-CFC, 2020 WL 4192613, at \*2 (D. Del. July 21, 2020).

That said, I'll briefly run through what Defendants say are the deficiencies in the FAC. First, Defendants say the FAC fails to state a plausible claim for the same reason it fails to adequately allege subject matter jurisdiction. I reject that argument because I conclude that there is subject matter jurisdiction.<sup>48</sup>

Second, Defendants point to the fact that the FAC alleges "on information and belief" that some of the claim limitations are met, including certain limitations related to botulinum toxin purification and potency.<sup>49</sup> Defendants say that renders the claims implausible. I reject that argument. For one thing, pleading upon information and belief is permissible where, as here, facts like the potency of Defendants' product and its method of manufacture are particularly within the defendant's knowledge and control.<sup>50</sup>

Moreover, there is no requirement that a complaint plead infringement on an element-by-element basis.<sup>51</sup> And, again, the allegations in the FAC put Defendants on notice of what Plaintiffs say is the infringing activity.

Defendants make a more specific argument regarding Counts XI and XII. Those counts allege that Revance has and will infringe the '567 patent, which contains product claims that cover substrates for botulinum toxin activity assays. The claims all require substrates that have the following characteristic: "under the appropriate conditions, resonance energy transfer is exhibited between said donor fluorophore and said acceptor fluorophore." According to Defendants, an exhibit attached to the FAC

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<sup>48</sup> The possibility that some of Defendants' actions might be protected by the statutory safe harbor does not make the infringement claims implausible. As discussed above, the allegations support a plausible inference that Revance has already infringed by stockpiling product. This case is thus distinguishable from cases in which the complaint itself left no reasonable inference other than that the allegedly infringing conduct was protected by the safe harbor defense. *See UCB, Inc. v. Catalent Pharma Sols., Inc.*, No. 21-38-GFVT, 2021 WL 5576327, at \*5 (E.D. Ky. Nov. 29, 2021) (collecting cases).

<sup>49</sup> (D.I. 23 at 17–20.)

<sup>50</sup> *Acera Surgical, Inc. v. Nanofiber Sols., LLC*, No. 20-980-CFC-JLH, 2021 WL 3187374, at \*3 (D. Del. July 28, 2021), *adopted*, 2021 WL 3375896 (Aug. 2, 2021); *NNCrystal US Corp. v. Nanosys, Inc.*, No. 19-1307-RGA, 2020 WL 616307, at \*3 (D. Del. Feb. 10, 2020); *DermaFocus LLC v. Ulthera, Inc.*, 201 F. Supp. 3d 465, 468 (D. Del. 2016).

<sup>51</sup> *Nalco*, 883 F.3d at 1350.

demonstrates that the assay method employed by Defendants does not take advantage of fluorescence energy transfer. I understand what Defendants are saying. However, at this stage, the Court is reviewing the claim for plausibility. [I]t is plausible that the product claims at issue [might later be construed to] only require a substrate capable of exhibiting energy transfer, even if Defendants' assay method doesn't take advantage of that phenomenon.<sup>52</sup>

For the reasons stated, I recommend that Defendants' motion to dismiss be denied.

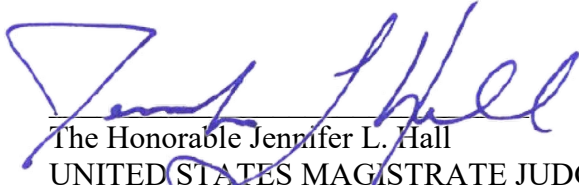
## II. CONCLUSION

I recommend that Defendants' motion (D.I. 22) be DENIED.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), (C), Federal Rule of Civil Procedure 72(b)(1), and District of Delaware Local Rule 72.1. Any objections to the Report and Recommendation shall be filed within fourteen days and limited to ten pages. Any response shall be filed within fourteen days thereafter and limited to ten pages. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court.

The parties are directed to the Court's "Standing Order for Objections Filed Under Fed. R. Civ. P. 72," dated October 9, 2013, a copy of which can be found on the Court's website.

Dated: July 21, 2022

  
The Honorable Jennifer L. Hall  
UNITED STATES MAGISTRATE JUDGE

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<sup>52</sup> See *Nalco*, 883 F.3d at 1349 (reversing district court's dismissal of patent infringement suit where the defendants' arguments for dismissal "boil[ed] down to objections to [the plaintiff's] proposed claim construction . . . , a dispute not suitable for resolution on a motion to dismiss").